



# **DARPA-Funded Animal Research**

## **Guidance for SBIRs and STTRs**



# Animal Use Regulations

- **Title 9, Code of Federal Regulations, Parts 1-3**  
“Animal Welfare Act (AWA) and Regulations”  
[http://www.aphis.usda.gov/animal\\_welfare/awa.shtml](http://www.aphis.usda.gov/animal_welfare/awa.shtml)
- **DoD Directive 3216.01**  
“The Use of Laboratory Animals in DoD Programs”  
<http://www.dtic.mil/whs/directives/corres/pdf/321601p.pdf>
- **DARPA Instruction No. 18 (DI-18 / AR 40-33)**  
“The Care and Use of Laboratory Animals in DoD Programs”  
[http://www.usapa.army.mil/pdffiles/r40\\_33.pdf](http://www.usapa.army.mil/pdffiles/r40_33.pdf)
- **DARPA Instruction No. 67 (DI-67)**  
“Funding Animal Use in Research”  
See Attachment



# Animal Research

- ALL efforts involving animal research must undergo a review by a trained DoD certified veterinarian as stated in DoDD 3216.01, including subcontractors.
  - USAMRMC Point of Contact: Ms. Lisa Fucci-Baker
  - Phone: (301) 619-6096
  - Email: Lisa.Fuccibaker@us.army.mil
- DoD approval is valid for the entire length of the contract, unless there is a major change: change in proposal/SOW, institution, PI, etc.
  - Institutional Animal Care and Use Committee (IACUC) approvals are only valid for three years.
- The contract can be awarded before approvals are granted with the inclusion of a prohibition clause, stating that performers are NOT allowed to use funds for animal research and testing until approvals are granted.
- New efforts using non-human primates, dogs, cats, and marine mammals require a site visit by a DoD veterinarian.
  - Timing of the site visit is at the discretion of the DoD vet and usually takes place after approval is granted.

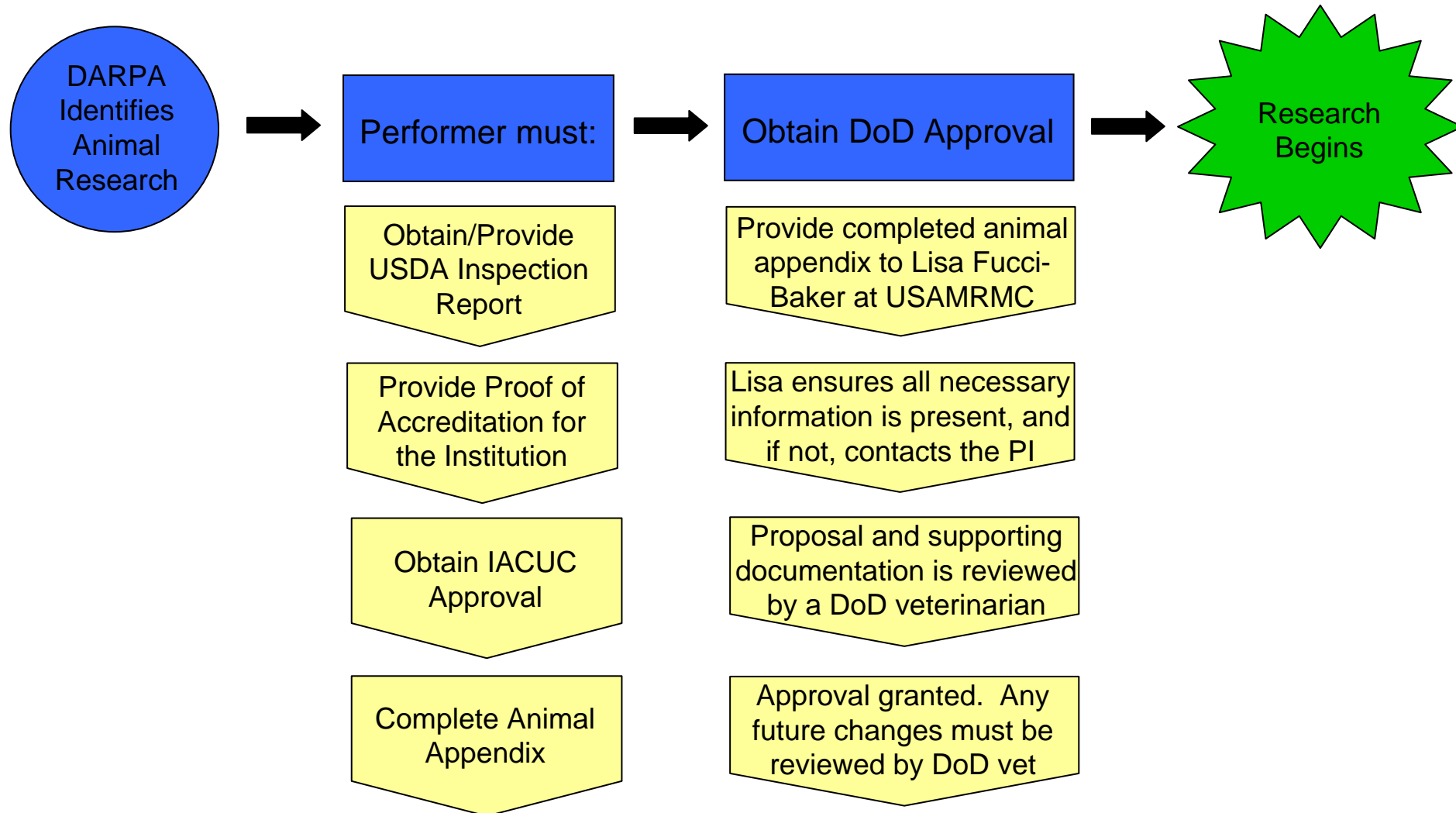


# Helpful Hints

- As soon as you know animal use will be involved, contact Lisa Fucci-Baker and DARPA's animal use contact, Megan Morgan at [morgan\\_megan@bah.com](mailto:morgan_megan@bah.com) or (703) 816-5469, to begin the approval process.
- The sooner you complete the animal appendix, the sooner your proposal can be approved.
- Information required in the animal appendix:
  - Copy of IACUC-approved protocol
  - Copy of All IACUC-approved protocol amendments/modifications
  - Species identification and rationale for selection
  - Experimental design
  - Literature search
  - Researchers' qualifications
  - PI's assurances
  - USDA Inspection Report
  - Institutional accreditations/assurances

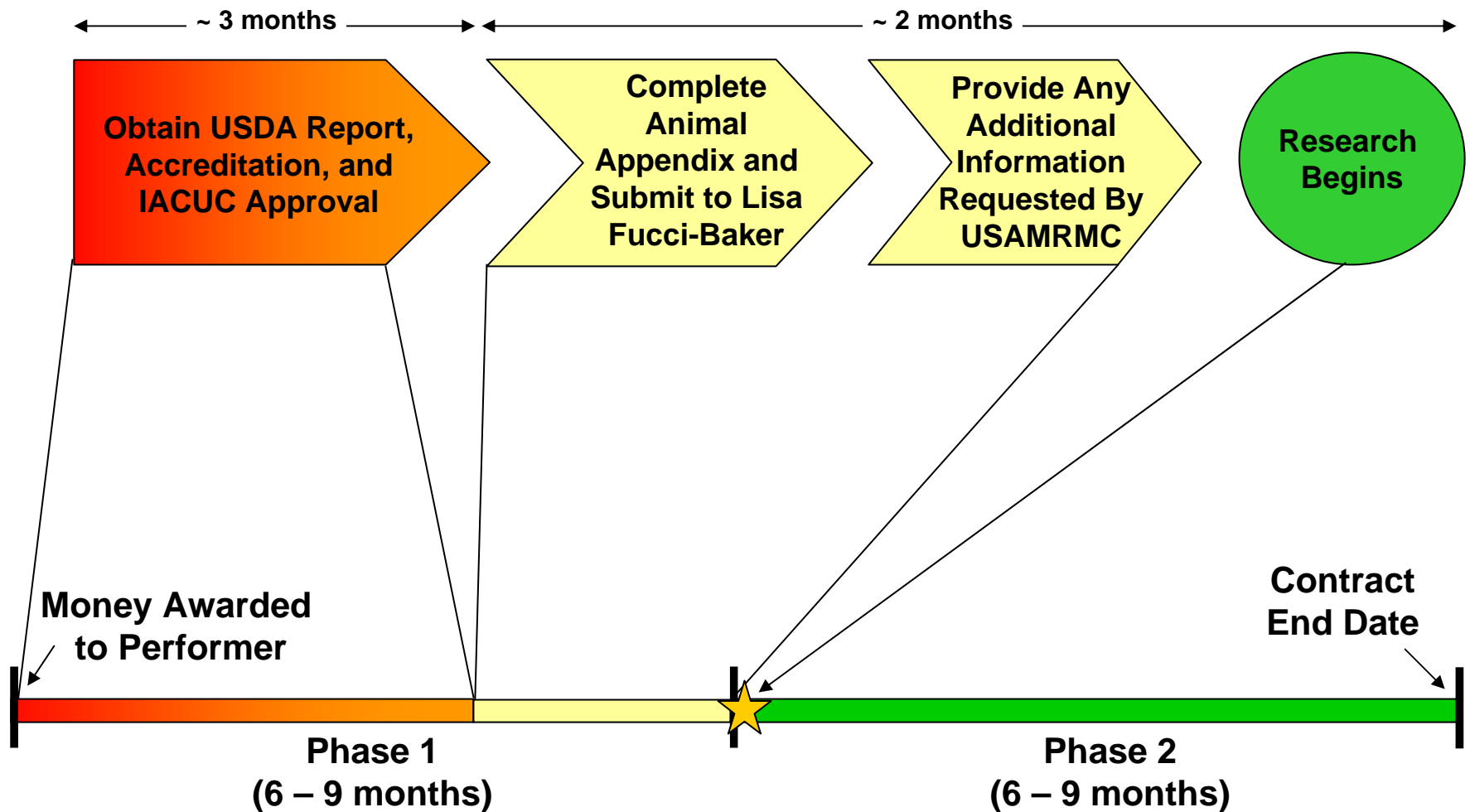


# Approval Process





# Approval Process Timeline



**\*\*Note: Absolutely NO money can be used on animal research and testing (including purchasing, housing, and caring) until DoD approval is granted.**



# Definitions

- **Animal** – Any live vertebrate animal that is being used or is intended for use in research, education, training, or testing.
- **Vertebrate** – A member of the subphylum Vertebrata (within the phylum Chordata), specifically, those chordates with backbones or spinal columns.
- **Accreditation** – Accreditation of animal care and use programs and facilities by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC).
- **IACUC** (Institutional Animal Care and Use Committee) – Committee at the institutional level that oversees and evaluates the institution's animal program, procedures, and facilities to ensure that they are consistent with the regulations and recommendations.
- **Prohibition Clause** – A clause in a contract forbidding an act or activity. For example, money can be awarded to a performer at the beginning of Phase 1 while they obtain proper approvals; however, the funds cannot be spent on any portion of the project involving animal research until proper approval is granted.